

Health Care Situation in the Treatment of Uncontrolled GINA Step 4/5 Patients in Germany

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Purpose: It has been estimated that, in 2019, 54,000 patients in Germany had uncontrolled GINA step 4/5 asthma. In the current study we analyzed which health care providers were involved in the management of these patients and their role in disease phenotyping.

Patients and Methods: The year 2019 was retrospectively analyzed using the IQVIATM LRx, a longitudinal anonymized prescription database, and the electronic, anonymized medical records database, the IQVIA Disease Analyzer.

Results: Of 54,000 uncontrolled GINA step 4/5 asthma patients in Germany, 52% had consulted both general practitioners (GPs) and pulmonologists, and 48% were seen exclusively by a GP. Of these 54,000 patients, 45% were being prescribed and were thus overusing short-acting β_2 -agonists (SABAs) and oral corticosteroids (OCS) for ≥ 2 years, 26% for ≥ 3 years, and 16% for ≥ 4 years. In most regions, pulmonologists saw one of their uncontrolled GINA step 4/5 asthma patients per week. Laboratory tests from consultations with a GP were available for only 10% of patients referred to a pulmonologist. In 50% of uncontrolled asthma patients treated according to GINA step 4/5, these were initiated by the pulmonologist, and 34% received laboratory testing within the first year (in GINA step 4/5 asthma, the numbers are 20% and 18%, respectively).

Conclusion: Fifty percent of uncontrolled asthma patients treated according to GINA step 4/5 were regularly seen by pulmonologists, who performed most of the phenotyping confirming their importance in the management of severe, uncontrolled asthma in Germany. To understand treatment pathways for these patients, further studies are needed.

Keywords: prescription database, biological treatment, laboratory test, uncontrolled GINA step 4/5 asthma, Germany

Introduction

Disease severity in asthma has been replaced by the level of asthma control in asthma recommendations over the years.^{1,2} According to the Global Initiative for Asthma (GINA) guidelines, patients with “severe asthma” require treatment at step 4 or 5 in order for their condition to be “controlled”. Some patients’ asthma, however, remains “uncontrolled” despite receiving step 4/5 therapy.³

In 2019, around 54,000 GINA step 4/5 asthma patients in Germany still showed evidence of uncontrolled asthma (oral corticosteroid [OCS] and/or short-acting β_2 -agonist [SABA] overuse), as described in a recently published study; there have been with no major improvements over recent years.^{4,5} Up to 15% of patients receiving step 4/5 treatment² are uncontrolled in some regions in Germany.^{2,4,5} Only 12,000 patients treated according to GINA step 4/5 are currently

receiving biologicals, which means there might be an opportunity for improvement.^{4,5} The objective of the current data analysis was to elucidate possible causes of this treatment gap.

To examine the different stations of the patient path where a gap in care may arise, it is important to analyze and understand which physician (GP or pulmonologist) is primarily in charge of treating severe/difficult to treat, uncontrolled asthma patients in Germany, how frequently patients are seen per year, whether phenotyping is consequently being performed in these patients in Germany, and whether there are regional differences. Improved insights into these processes might be useful to improve treatment and management of these patients.

Materials and Methods

Study Design

Data in this retrospective study was collected in 2019 (January to December) before the COVID-19 pandemic started, and analyzed in 2021. The study design and methods have been published previously.^{4,5} The study was supported by an expert committee of pulmonologists from private practices and hospitals. In cooperation with GlaxoSmithKline, the methodology, patient cohorts, and data analyses were defined.

Data Sources

Patient quantification was performed using the IQVIA LRx as the main data source containing around 80% of retail pharmacy prescriptions in the German statutory health insurance system. Relevant information such as substance, prescribed product, and pack (Pharmazentralnummer (PZN), a unique identifier of each product, dose and dosage form), date of prescription, and specialty of the prescriber were extracted from the IQVIA LRx as well. In addition, patients' age and gender and prescribers' location at the 63 district level in Germany were extracted.

To validate different IQVIA LRx results and to analyze data about phenotyping we used the Disease Analyzer database of IQVIA, which contains information on office-based general practitioners (GPs), pulmonologists and pediatricians in a representative sample of Germany.⁶ Disease Analyzer contains anonymized electronic records including diagnoses (as encoded by ICD-10), prescriptions, sick leaves, referrals and examination results such as BMI and standard laboratory tests.

Human Ethics Statement

The database used includes only anonymized data, in compliance with the regulations of the applicable data protection laws. German law allows the use of anonymous electronic medical records for research purposes under certain conditions. According to this legislation, it is not necessary to obtain informed consent from patients or approval from a medical ethics committee for this type of observational study that contains no directly identifiable data.

Because patients were only analyzed as aggregates and no protected health information was available for examination, no Institutional Review Board approval was required for the use of this database or the completion of this study.

Selection of Uncontrolled Asthma Patients Treated According to GINA 4/5

In the subset of patients receiving treatment according to GINA step 4/5, uncontrolled asthma was expected as a proxy in patients treated with high doses of SABA and/or OCS. Definitions for high OCS use were a score of ≥ 2 , with pulmonologists' prescription scored as 1.0, and GPs/other specialists' prescriptions scored as 0.75. High-dose OCS was determined from tablet strength and size of prescribed pack. The strengths and pack size thresholds have been validated with dosage recommendations in Disease Analyzer data, validated by medical experts and published previously.⁴ Definitions of high SABA use were ≥ 3 SABA prescriptions in 2019 with no prescriptions for ICS-maintenance therapy. The rationale was to count only SABA prescriptions that were provided outside regular check-ups and maintenance medication refills.

Management of Uncontrolled Asthma Patients Treated According to GINA 4 or 5

From the dataset of patients receiving asthma therapy according to step 4/5 of the GINA guidelines who were still uncontrolled, we identified which physician was primarily treating the patient or whether their care was managed through

collaboration by different physicians, using the IQVIA LRx as the main data source. The IQVIA Disease Analyzer database was used to quantify how often phenotyping of eosinophiles or IgE was carried out by blood test in the diagnosis and management of uncontrolled GINA step 4/5 asthma.

Results

Treating Physicians

In 2019, around 625,000 patients received treatment for asthma scored at a severity grade of 4/5 according to the GINA guidelines in Germany; 54,000 of these had uncontrolled asthma according to the selection criteria used. In 52% of these uncontrolled patients, treatment was provided by both a GP and a pulmonologist, and received at least one prescription from one of the 2700 pulmonologists in Germany (Figure 1).

The remaining 48% of patients were exclusively treated by one of the 45,000 GPs in Germany. The patients' profiles differed between those treated solely by a GP and those with additional pulmonologist visits. In the group treated exclusively by GPs, SABA overuse was observed in 63%, and 42% used high amounts of OCS. In the group of patients treated by GPs and pulmonologists, OCS overuse was observed in 68%, and 41% used high amounts of SABAs (Figure 1). The number of GINA step 4/5 asthma patients seen on average by a pulmonologist per year was 142, and 16 of them were uncontrolled; in comparison, only one of 9 GINA step 4/5 asthma patients was uncontrolled and seen by a GP per year (including patients co-treated by pulmonologists) (Figure 1).

There were no major regional differences throughout Germany in the number of uncontrolled GINA step 4/5 patients seen by a pulmonologist (Figure 2).

16 Uncontrolled GINA step 4/5 Asthma Patients per Pulmonologist per Year (Mean) in Germany in 2019 (1 per GP)

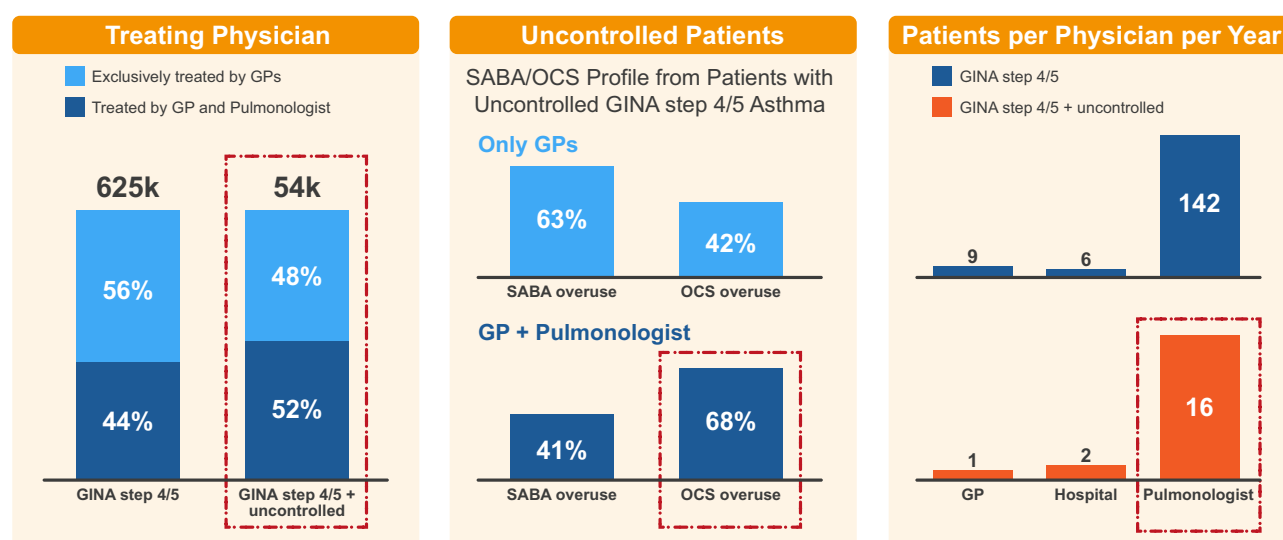


Figure 1 Overview of physicians treating uncontrolled GINA step 4/5 asthma in 2019 in Germany. Of all patients with severe, uncontrolled asthma, 52% were treated by both a GP and pulmonologist and 48% exclusively by GPs. The patient profiles differ: GPs primarily over-prescribe SABA (63%), while pulmonologists primarily over-prescribe OCS (68%). The mean number of uncontrolled GINA step 4/5 asthma patients seen by pulmonologists per year was 142 compared to only 1 seen by a GP per year. **Notes:** Mod. acc. IQVIA LRx MAT 12/2019; *Number of hospital physicians overestimated because no differentiation between physicians in outpatient department and hospital possible.

Abbreviations: GP, General Practitioner; SABA, short-acting β_2 -agonist; OCS, oral corticosteroid.

No Major Regional Differences in the Distribution of Uncontrolled GINA step 4/5 Asthma Patients Treated by Pulmonologists in Germany

16 uncontrolled GINA step 4/5 asthma patients per pulmonologist per year seen at least 1x per quarter

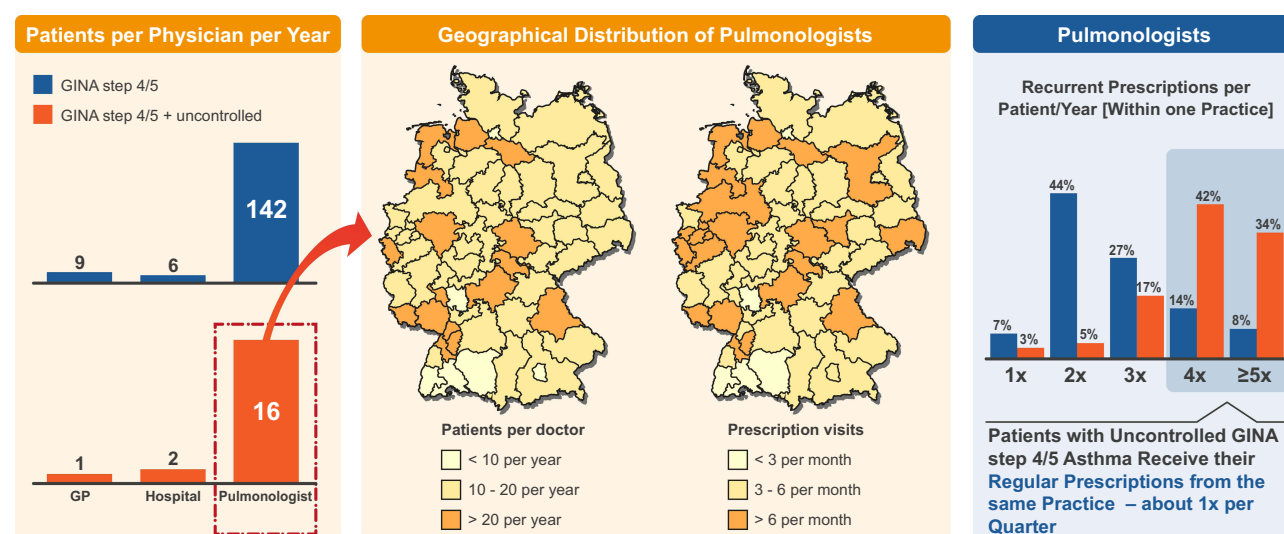


Figure 2 Overview of the regional distribution of pulmonologists treating patients with uncontrolled GINA step 4/5 asthma in Germany in 2019. No major regional differences in the distribution of uncontrolled GINA step 4/5 asthma patients treated by pulmonologists in Germany. Patients with uncontrolled GINA step 4/5 asthma received their regular controller prescriptions from the same practice about once per quarter.

Abbreviation: GP, general practitioner.

Most pulmonologists saw 10–20 uncontrolled GINA step 4/5 asthma patients per year, but some treated more than 20 per year. In most of the regions, the mean number of visits resulting in the receipt of a prescription is 3–6 per month, but in some regions it is >6 per month (Figure 2). According to data from the IQVIA Disease Analyzer of anonymized patient records, patients with uncontrolled GINA step 4/5 asthma received their regular prescriptions from the same pulmonologist practice about once per quarter (Figure 2). In most regions, pulmonologists saw one of their uncontrolled GINA step 4/5 asthma patients per week.

Phenotyping

According to the available anonymized records of 6000 patients with GINA step 4/5 asthma treated by pulmonologists (including lab data of IgE tests and eosinophil counts), the laboratory diagnostic test performed at the first consultation and during treatment was analyzed. For 10% of patients, their laboratory tests were performed in the GP's office prior to referral to a pulmonologist (after no later than 30 days) (Figure 3).

In patients with GINA step 4/5 asthma, 20% had their laboratory diagnostic tests performed during their first consultation with a pulmonologist and 18% during the first year (Figure 3), which increased slightly with the number of prescriptions issued by the same practice. In 50% of uncontrolled asthma patients receiving treatment according to step 4/5 of the GINA guidelines laboratory diagnostic tests were performed by pulmonologists during the first consultation. In 34% of these patients, at least one of these measures was performed during the first year (Figure 3).

Duration of Uncontrolled GINA Step 4/5 Asthma

During the years 2015–2019, of asthmatic patients receiving therapy according to GINA severity level 4/5 and in receipt of at least 1 prescription from a pulmonologist in 2019, 45% demonstrated continuous OCS and SABA overuse as an indication of uncontrolled asthma for at least 2 years; each fourth patient (26%) demonstrated maintenance OCS and SABA overuse for at least 3 years and 16% of patients for 4 or more years (Figure 4).

In 50% of Patients with Uncontrolled GINA step 4/5 Asthma Laboratory Diagnostic is Performed at First Consultation of a Pulmonologist

Laboratory Diagnostics Performed by Pulmonologists – First Consultation and Longitudinal

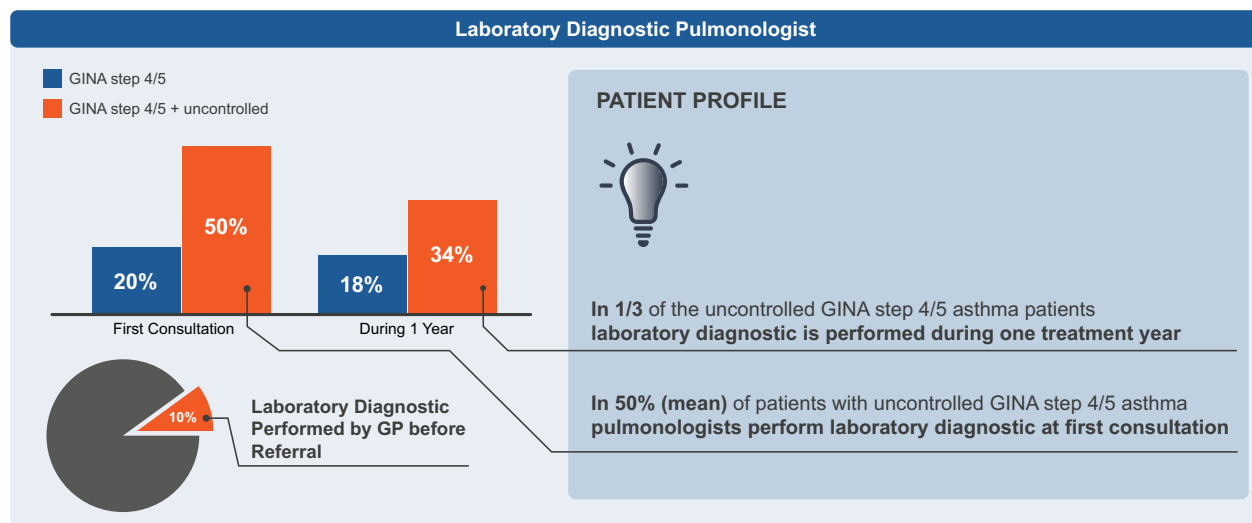


Figure 3 Overview of laboratory diagnostics performed by pulmonologists at first consultation and longitudinally. In 50% of patients with uncontrolled GINA step 4/5 asthma, laboratory diagnostics were performed at first consultation; one-third underwent laboratory diagnostics during one treatment year.

Notes: Mod. acc. IQVIA Disease Analyzer 01/2019–06/2020; ~6,000 available patients with GINA step 4/5 asthma treated by GPs or pulmonologists.

Abbreviation: GP, General Practitioner.

Duration of Uncontrolled GINA step 4/5 Asthma

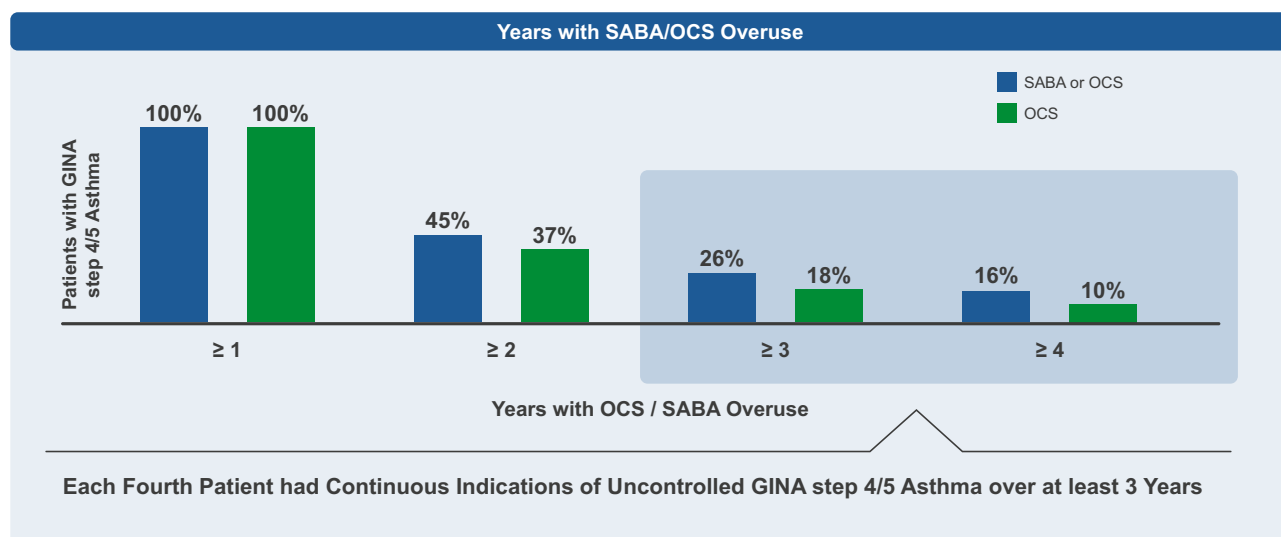


Figure 4 Duration of uncontrolled GINA step 4/5 asthma. Every fourth patient had continuous indications of uncontrolled GINA step 4/5 asthma over at least 3 years (years analyzed 2015–2019).

Notes: Mod. acc. IQVIA LRx MAT 12/2019; Patient cohort “GINA step 4/5 asthma” with at least 1 prescription from a pulmonologist.

Abbreviations: SABA, short-acting β 2-agonist; OCS, oral corticosteroid.

Discussion

The present study aimed to analyze which health care providers are involved in the management of uncontrolled asthma in patients under GINA 4/5 treatment in Germany, including the regional situation, and to understand the role of phenotyping in these patients in order to gain insights into the different processes that might offer opportunities for improvement.

Of the 54,000 uncontrolled asthma patients under GINA 4/5 treatment, 52% were managed by one of 2700 pulmonologists⁷ and 48% by one of 45,000 GPs.⁷ On average, every pulmonologist treated 16 uncontrolled GINA step 4/5 asthmatics per year. Those patients with uncontrolled GINA step 4/5 asthma had outpatient visits on average once every three months, mainly because patients received their prescriptions every three months from the same practice. Uncontrolled patients, in particular, appear to contact their pulmonologist more regularly. In the different regions of Germany, this situation was similar and there were no major differences. So, pulmonologists have the best access to uncontrolled GINA step 4/5 asthma patients because of the high numbers per practice and their regular visits.

On the other hand, according to the IQVIA Disease Analyzer,⁶ 1 in 4 patients treated according to level 4/5 of the GINA guidelines and whose asthma was not under control had permanent characteristics of being not controlled over at least 3 years; sometimes it takes years to diagnose severe, uncontrolled asthma and treat it adequately. Of uncontrolled GINA step 4/5 patients treated by GPs and pneumologists, 68% demonstrated OCS overuse and 41% SABA overuse. These results are comparable to the results of other studies describing OCS^{8–10} and SABA overuse^{11,12} and seem to be comparable to the results in other European countries.¹² Janson et al 2020 used a SABA overuse definition comparable to ours (≥ 3 canisters per year) and found SABA overuse in approximately one-third of mild to severe asthma patients across Europe, despite the different healthcare and reimbursement policies of each country; indeed, some countries even exceeded the numbers seen in Germany.¹² The question arises of whether the limited laboratory diagnosis and phenotyping might be one reason for this situation. In a targeted literature review from 2020 no high-quality data on biomarker prevalence could be identified in Germany.¹³ On the other hand, the importance of phenotyping, especially in severe asthma, has been described.^{14–17} As shown in our analysis, an uncontrolled GINA step 4/5 asthma patient underwent more laboratory diagnostics than a GINA step 4/5 asthma patient. Irrespective of the number of consultations, pulmonologists initiate laboratory diagnostics in around half of uncontrolled step 4/5 asthma patients during the first consultation, while only in 20% of GINA level 4/5 asthma patients. During the first year, 66% of GINA level 4/5 uncontrolled asthma patients and 82% of GINA level 4/5 asthma patients were not phenotyped/blood tested. That means that in some uncontrolled GINA 4/5 asthma patients laboratory tests to phenotype patients were neither performed at first visit nor during follow-ups, and no follow-up tests were performed to improve asthma management. In a recently published analysis of retrospective medical records of German COPD patients, the number of laboratory tests performed was even lower.¹⁸ In 7.2% of patients during 2017–2018, routine measures of blood eosinophils for initial diagnosis were performed, but not on a regular basis.¹⁸ This test seems to be not yet implemented in COPD.¹⁸ Possible reasons for the low number of routine laboratory tests performed for severe asthma patients could be commercial hurdles to repeated laboratory tests or missing standards to prioritize phenotyping of severe, uncontrolled asthma patients. Phenotyping, on the other hand, has improved clinicians' approach to characterize patients with asthma.¹⁹ Thus the identification of patients using biomarkers in addition to clinical symptoms offers the possibility to perform precision medicine and personalized treatment of asthma.¹⁹ It has therefore been recommended that laboratory tests should be performed for severe asthma patients at each initial consultation with a pulmonologist, especially in those with uncontrolled asthma. This approach should become the standard of care, and might be more useful and less time consuming than current costly prioritization of patients using, for example, digital patient profiles, rapid tests, etc.

In summary, comparable to other European countries, a high number of asthma patients treated according to GINA stage 4/5 are still not controlled in Germany. Our analysis identifies hurdles that might be involved in the development of treatment gaps in uncontrolled asthma patients in Germany, such as the low number of routine laboratory tests performed for severe asthma patients and the fact that phenotyping is consequently not being performed. Pulmonologists play a crucial role in overcoming these gaps, because they primarily treat these group of patients. However, they should be

supported by a reduction of commercial hurdles and the availability of standards to prioritize phenotyping, especially in the management of severe, uncontrolled asthma.

A limitation of the study is that it cannot be excluded that the high overuse of SABA and OCS is caused by not taking the asthma medication or a false application, although this is regularly controlled in pneumologists' practice, and the criterion for uncontrolled asthma is a proxy. A further limitation is the retrospective design, which has a potential risk of bias. But the large data pool of around 80% of the prescriptions claimed in retail pharmacies in Germany and the IQVIA LRx data pool containing most relevant information from prescriptions that was available using this retrospective design as well as the representation of real life practices should outrank this possible risk.

Conclusion

Comparable to other European countries, a high number of asthma patients treated according to GINA stage 4/5 are still not controlled in Germany. Pulmonologists play a major role in overcoming the management gap in uncontrolled GINA step 4/5 asthma in Germany because they treat more than 50% of these patients regularly and perform most of the phenotyping. Further data is needed about the treatment decisions in severe, uncontrolled asthma in Germany and the chances for improvement in patient management.

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Disclosure

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